

**JUDGE DANIELS**

**TO BE FILED UNDER SEAL**

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

**18 CV 4599**

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PLAINTIFFS UNDER SEAL

v.

\_\_\_\_\_  
DEFENDANTS UNDER SEAL

) **Civil Action No.**  
)  
)  
)

) **FILED UNDER SEAL**  
)

) **JURY TRIAL DEMANDED**  
)

**COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS  
UNDER 31 U.S.C. § 3729 ET SEQ. AND STATE LAW COUNTERPARTS**

FILED  
U.S. DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK  
MAR 9 2023

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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA, ex rel. )  
SWFC LLC, and on behalf of the STATES )  
of CALIFORNIA, COLORADO, )  
CONNECTICUT, THE DISTRICT OF )  
COLUMBIA, FLORIDA, ILLINOIS, )  
INDIANA, MARYLAND, )  
MASSACHUSETTS, NEW JERSEY, )  
NEW YORK, OKLAHOMA, TEXAS, )  
AND VIRGINIA, )

Plaintiffs,

v.

STIMWAVE TECHNOLOGIES, INC., )  
STIMWAVE LLC, and LAURA TYLER )  
PERRYMAN, )

Defendants. )

Civil Action No. \_\_\_\_\_

**FILED UNDER SEAL**

**JURY TRIAL DEMANDED**

**COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS  
UNDER 31 U.S.C. § 3729 ET SEQ., AND STATE LAW COUNTERPARTS**

**INTRODUCTION**

1. Plaintiff/Relator, SWFC LLC (“SWFC” or “Relator”), on its behalf and on behalf of the United States of America, and on behalf of the State of California, State of Colorado, the State of Connecticut, the District of Columbia, the State of Florida, the State of Illinois, the State of Indiana, the State of Maryland, the State of Massachusetts, the State of New Jersey, the State of New York, the State of Oklahoma, the State of Texas, and the State of Virginia (collectively, the “Qui Tam States”), brings this qui tam action against the Defendants, Stimwave Technologies, Inc. and Stimwave LLC (collectively, “Stimwave” or the “Company”) and their majority owner, co-founder, and Chief Executive Officer Laura Tyler Perryman (“Perryman”) (together, Stimwave and Perryman shall be referred to herein as the “Defendants”).

2. Relator brings this action on behalf of the United States and the Qui Tam States to recover damages and civil penalties under the False Claims Act (“FCA”) and State qui tam statutes against Defendants for causing the submission of false or fraudulent claims; for making, using, or causing to be made or used false records or statements material to false or fraudulent claims; and for conspiring to do all of the same.

3. Relator brings this action against the Defendants pursuant to the following State qui tam provisions: the California False Claims Act, Cal. Gov’t Code § 12650 et seq.; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-304 et seq.; the Connecticut False Claims Act, Conn. Gen. Stat. § 4-274 et seq.; the District of Columbia False Claims Act, DC Code §§ 2-381.01 through 2-381.09; the Florida False Claims Act, Fla. Stat. § 68.081 et seq.; the Illinois False Claims Whistleblower Reward and Protection

Act, 740 Ill. Comp. Stat. § 175/1 et seq.; the Indiana Medicaid False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.7-1 through 5-11-5.7-18; the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-Gen. § 2-601 et seq.; the Massachusetts False Claims Act, Mass. Gen. Laws, Chapter 12, §§ 5A -5O; the New York False Claims Act, N.Y. State Fin. Law. § 187 et seq.; the New Jersey False Claims Act, N.J.S.A. 2A:32C-1 et seq.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §§ 5053.1 through 5053.7; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 et seq.; and the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 et seq. (collectively, the “State qui tam statutes” or “Qui Tam Statutes”).

4. Relator seeks civil penalties, damages, declaratory relief, injunctive relief and such other relief as is available under the FCA and/or the State qui tam statutes, and demands a trial by jury for all claims for which the right to a jury trial is authorized.

5. This case arises from the Defendants’ unlawful participation in (a) the presentment to the federal government and the Qui Tam States of false or fraudulent claims for payment under federal health care programs relating to the medical device products designed, manufactured, marketed and sold by Stimwave, and (b) the making or use of false records or statements material to the false or fraudulent claims relating to the Stimwave medical device products.

6. Stimwave is a medical device company engaged in the development, manufacture, commercialization, and marketing of wireless microsize injectable medical devices for neurology markets. The company provides MicroStim, a wireless technology which can be used in microsize injectable medical devices for neurology markets. Its products include Freedom SCS System, a Spinal Cord Simulator, which is used for the

relief of chronic low back and leg pain and StimQ PNS System, a Peripheral Nerve Stimulator, which treats chronic pain by targeting the peripheral nerve affiliated with the chronic pain.

7. Patients who have been treated by Stimwave-trained physicians using the StimQ PNS System have been subjected to invasive, improper, unjustified, medically unnecessary, high risk and costly medical procedures that were undertaken to treat chronic pain by targeting the peripheral nerve affiliated with the chronic pain. Defendants' conduct caused these patients to be subjected to unnecessary procedures.

8. Defendants knowingly caused the submission of claims for reimbursement to Medicare and other federally-funded health care programs for these improper and unnecessary medical procedures. Defendants have knowingly perpetuated a fraud upon the United States and injured vulnerable patients in the process. Defendants instituted this sham with the specific intent to induce sales of Stimwave's products by key accounts.

9. Relator has witnessed the fraud and Defendants' predatory surgical practices during his employment at Stimwave. Additionally, multiple other sales representatives and physicians trained by Stimwave have complained to Defendants about Defendants' unethical procedures and expressed concern about the health and welfare of vulnerable patients. These complaints fell on deaf ears and Defendants failed to take any action to protect these patients. Stimwave-trained physicians unnecessarily perform surgical and invasive procedures that serve no medical benefit in order to bill for the additional unnecessary procedures.

10. The sole purpose of this practice of training and instructing physicians to perform multiple procedures where only one procedure was clinically necessary was to

submit additional bills to Medicare for the additional procedures, in order to increase reimbursements for Stimwave's medical devices and incentivize the physicians to buy its products.

11. Significantly, Defendants' pattern of marketing to and training physicians to require patients to undergo multiple surgical procedures unnecessarily, placed the patients at greater risk of complications including infections.

12. Defendants' scheme also involved a business model that incentivized physicians to use Stimwave's medical devices by rewarding them with lucrative consulting agreements and investment opportunities in Stimwave's business, as an illegal quid pro quo. In addition, Defendants offered illegal remuneration to the physician-consultants in the form of reimbursement and discounted medical devices, to induce the physicians to use Stimwave's medical devices while performing certain surgical procedures.

13. Additionally, Stimwave's medical devices suffer from design and/or manufacturing defects that result in lead failure, migration, or fracture. As a result of the defects, the medical devices do not work as intended in many patients and cause significant patient harm.

14. In order to avoid product recall and maintain its rapid market growth, Defendants have not informed doctors, patients, or the FDA of the defects. By failing to report significant adverse events with the use of Stimwave's medical devices, Defendants caused patients to unnecessarily undergo multiple revisional procedures, many of them requiring general anesthesia.

15. Defendants' unlawful conduct has had a direct adverse financial impact on Medicare, Medicaid, and other government-funded healthcare programs. For example, the

federal government, primarily through Medicare and Medicaid, pays for many billions of dollars in medical supplies, medical devices and equipment and services annually nationwide. Defendants knew that the federal government would ultimately pay for a large portion of its medical products sold to physicians and hospitals. As such, Defendants are liable for knowingly causing physicians to submit false claims to get government funds paid or approved by the United States.

**I. JURISDICTION AND VENUE**

16. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. §§ 3730, 3732(a), 28 U.S.C. § 1331 and 28 U.S.C. § 1345.

17. The Court has original jurisdiction over the State law claims pursuant to 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367 because this action is brought under State laws for the recovery of funds paid by the Qui Tam States, and arises from the same transactions or occurrences brought on behalf of the United States under 31 U.S.C. § 3730.

18. This Court has personal jurisdiction over the Defendants because, among other things, Defendants transact business in this judicial district and Defendants engaged in wrongdoing in this judicial district.

19. Venue is proper in this judicial district under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). The Defendants transact business within this judicial district, and numerous acts proscribed by 31 U.S.C. § 3729 occurred in this judicial district.

20. The causes of action alleged herein are timely brought because of, among other things, efforts by the Defendants to conceal from the United States its wrongdoing in connection with the allegations made herein.

## **II. PARTIES**

### **A. PLAINTIFF/RELATOR**

21. Plaintiff/Relator SWFC LLC, a Delaware limited liability company, brings this action on behalf of itself, the United States of America and the Qui Tam States named herein. Its principal place of business is c/o Seeger Weiss LLP, 77 Water Street, New York, NY 10005. Among the members of SWFC is a current or former Stimwave employee with personal knowledge of the fraudulent scheme alleged in this Complaint (the “Relator”). The Relator possesses personal knowledge and experience regarding Stimwave’s sales promotion activities, including personal contact with the employees and executives of Stimwave who have committed the violations of law alleged herein. The personal knowledge of SWFC is not distinct from that of the Relator.

22. Relator was employed as a sales representative of Stimwave until he resigned from the Company after investigating the Company’s unlawful activities that resulted in the illegal sale and reimbursement of Stimwave’s medical device products. After learning that Stimwave had marketed to and trained physicians to perform medically unnecessary procedures, Relator brought allegations of the wrongdoing described in this Complaint to the attention of Stimwave’s executives and was told that physicians need to perform the procedure in order to obtain reimbursement sufficient to justify the cost of Stimwave’s medical devices.

23. Relator has personal knowledge and experience regarding Defendants’ activities, including personal contact with the employees and executives who have committed violations of law alleged herein. Relator is an original source of the allegations in this Complaint, and these allegations are not based upon publicly-disclosed information. Prior to filing this Complaint, Relator provided the Government with written disclosure of

substantially all material evidence and information that Relator possessed, including numerous documents and a preliminary disclosure statement, in accordance with 31 U.S.C. §§ 3729(a)(7)(A)-(C), 3730(b)(2).

**B. DEFENDANTS**

24. Defendant Stimwave Technologies Inc. is a Delaware corporation that was incorporated on December 9, 2010. Defendant Stimwave LLC is a Nevada limited liability company that was organized on September 23, 2014. On information and belief, Stimwave Technologies Inc. and Stimwave LLC operate as a single enterprise with its principal place of business in Florida.

25. Stimwave is a medical device company that is owned, and was co-founded by its Chief Executive Officer, Defendant Laura Tyler Perryman. Stimwave manufactures, designs, develops, and markets implants and instruments, including medical devices and technologies, used in the treatment of chronic pain. Stimwave's principal mailing address is 1510 Alton Road, Suite 417, Miami Beach, FL 33139. Stimwave is a privately-held company and has approximately 50 to 75 employees.

26. As described more fully herein, Stimwave engaged in the development, manufacture, commercialization, and marketing of wireless microsize injectable medical devices for neurology markets that are paid or reimbursed by various government programs, including Medicare, Medicaid, the Department of Defense's TRICARE/CHAMPUS programs, the Department of Veterans Affairs' CHAMP/VA program, and the Federal Employees Health Benefit Plan. At all times material hereto, Stimwave manufactured, marketed and sold medical devices throughout the United States, including within this judicial district.

27. Current and former Stimwave executives with knowledge of the fraudulent activities alleged herein include Perryman; Patrick Tompkins, Executive Vice President of US Sales; Michael Baja, Sales Director; Chad Andersen, Senior Director of Product Marketing; Geert Herecant, Vice President of OUS Sales; Bertan Bakkaloglu, Vice President of Engineering; Elizabeth Greene, Vice President of Regulatory; and Ron Perryman, Senior Director of Operations.

28. Defendant Perryman controls Stimwave and is the principal architect of the scheme to cause Stimwave-trained physicians to perform unnecessary procedures in order to seek additional reimbursements. Perryman is an individual who resides in Miami Beach, Florida.

### **III. DEFENDANTS' SCHEME TO INDUCE USAGE OF STIMWAVE'S MEDICAL DEVICES**

29. The allegations of false claims herein involve Stimwave's Freedom SCS System, a Spinal Cord Simulator, which is used for the relief of chronic low back and leg pain and StimQ PNS System, a Peripheral Nerve Stimulator, which treats chronic pain by targeting the peripheral nerve affiliated with the chronic pain (the "Products").

30. Neurostimulation is a procedure that uses an electrical current to treat chronic pain. Peripheral nerve stimulation ("PNS") and spinal cord stimulation ("SCS") are two types of electrical nerve stimulation. In either, a small pulse generator sends electrical pulses to the nerves (in peripheral nerve stimulation) or to the spinal cord (in spinal cord stimulation). These pulses interfere with the nerve impulses that make patients feel pain.

**A. STIMWAVE'S MEDICAL DEVICES**

31. Medical devices must be cleared by the Food and Drug Administration (“FDA”) before a vendor can market the device in interstate commerce.

32. Companies can bypass the FDA’s premarket approval process if they can show that their proposed device is “substantially equivalent” to other commercially available devices. Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act provides for marketing of a medical device if the device is deemed “substantially equivalent” to other predicate devices marketed prior to May 28, 1976. *See generally* 21 U.S.C. § 360e(b)(1); 21 CFR § 814.1(c)(1).

33. Stimwave sought and obtained FDA clearance to market the products under Section 510(k). No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted by Stimwave with regard to the Products.

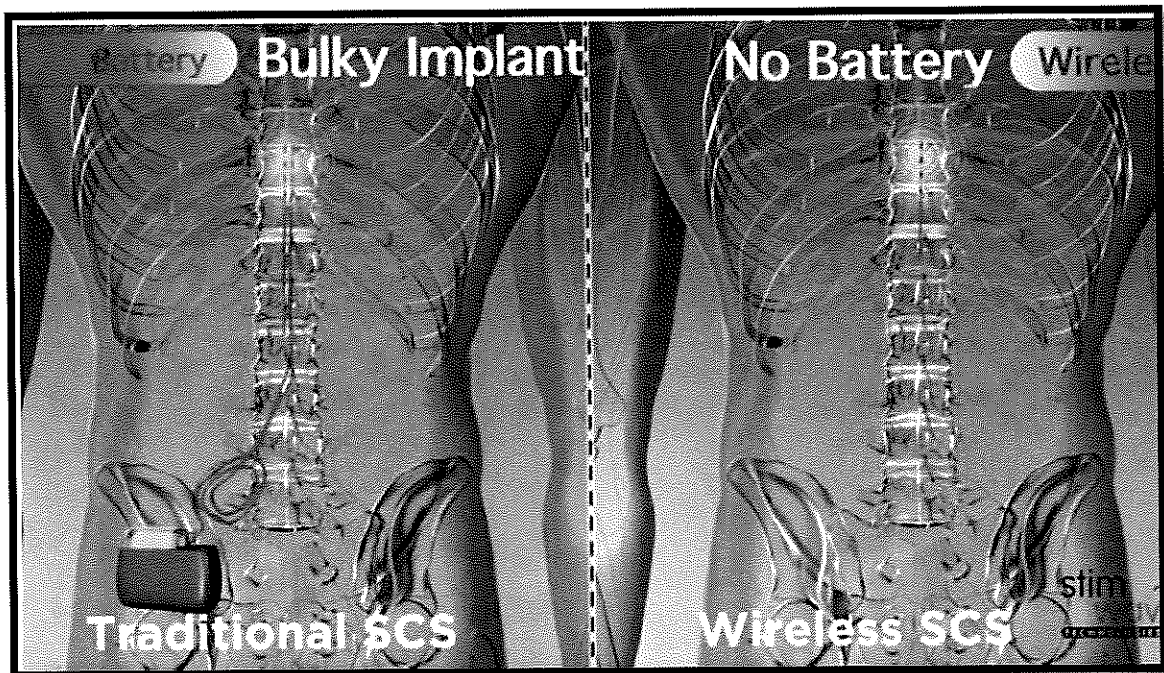
34. In Stimwave’s 510(k) submissions to the FDA, Stimwave cited various medical devices as substantial equivalents, including Medtronic Matriix 3271/3272 (K934065), Medtronic Xtrel, Model Number 3425 (K883780), and ANS Renew (K000852).

35. Significantly, all of the “substantially equivalent” products are wired neurostimulator placements using a large generator/battery type device (generally the size of a hockey puck) that is implanted in a subcutaneous “pocket” incision in the patient. These products utilize the generator to send power and signals to the electrodes to produce stimulation.

36. Because of the cumbersome equipment and stimulation systems, the surgical procedure remains invasive with placement of long stimulation leads, connecting

wires and sizeable battery that requires to be placed inside the body. There are not only cosmetic concerns with the bulky battery and skin incisions, but also a high risk of adverse events like lead erosion, fracture, infection.

37. Unlike the equivalent products, Stimwave's products are wireless and do not use a generator and thus do not require the medical procedure to implant the generator. Stimwave's stimulators have a built in wireless receiver that consists of a microcircuit and antennas. The stimulator receives power through the skin, and delivers the stimulation program out of the electrodes:



38. Stimwave touts its products as revolutionizing the industry with sleek, easily wearable options giving patients and clinicians affordable choices for pain management:

# FierceBiotech

BIOTECH RESEARCH IT CRO MEDTECH

MedTech

## Startup gains FDA clearance for first tiny, injectable neuromodulation system for back pain

by Stacy Lawrence | Dec 3, 2014 10:45am



Chronic back pain is notoriously difficult to treat with existing surgical or therapeutic options. Now physicians can add another tool to their arsenal that targets the pain locally, without requiring surgery or an external device. The FDA has cleared Stimwave Technologies' Freedom Spinal Cord Stimulation (SCS) System, which the company says is the smallest available neuromodulation device.

The device is "the world's smallest, wireless, injectable neurostimulator," according to Stimwave, and it relies upon recent advances in nanotechnology. It's already marketed in Europe and expected to be commercially available in the U.S. in January.

The FDA cleared the device for relief of chronic back and leg pain. It includes an injectable microchip and electrodes that deliver small electrical pulses to the surrounding nerves that cause the brain to remap pain signals, thereby providing pain relief.

"This technology is no longer an academic-type science experiment, but a real, viable innovation that can immediately start being utilized by patients in pain," Stimwave chairman and CEO Laura Tyler Perryman said in a statement.

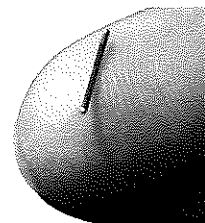
The device is only 0.25 centimeters long and can fit through a standard-gauge needle for placement without surgery. It is fixed in place with an anchor, so it's not expected to move within the body. It is intended to be a permanent, long-term implant.

Also, the system is designed to allow an MRI without the removal of the implant, which the company said is a unique feature. The SCS system doesn't require batteries, making it easier to achieve the minuscule size.

"Now people in pain will have additional options including the ability to receive a permanent implant with a far less invasive and complicated surgery, while avoiding the cumbersome long-term issues with recharging, as is the case today with other systems," said Dr. David Kloth, Medical Director of the Connecticut Pain Care Center, said in a statement.

The Miami Beach, FL-based Stimwave came out of the Arizona life sciences incubator BioAccel.

- here is the release



*Stimwave's Freedom Spinal Cord Stimulation (SCS) System--Courtesy of StimWave*

39. Stimwave's products are simple long thin tubes. At one end of this tube are the metal electrodes, which stimulate the spinal cord. Also inside the lumen (inside body) of the lead is the receiver (instead of a generator), which receives wireless signals from an external wireless device. The receiver is essentially a microchip. On a patient's body will

be an antenna, which produces a microwave. This antenna sends a microwave signal to the receiver. The receiver (via the microchip), then “kicks in” and sends signals to the electrode to produce stimulation.

40. With Stimwave’s medical devices, if the receiver is too deep in the epidural space, the only way to stimulate the receiver microchip is by utilizing a copper wire that goes into the lead. The antenna’s microwave is picked up by the copper wire, which in turn stimulates the receiver and then the electrodes (the “receiver stylet”). The end of the lead or copper wire is placed just under the skin. The physician will snip and suture around the lead itself to minimize lead migration issues.

41. The copper receiver stylet is only necessary when the receiver component is too deep to receive signals from the antenna. The copper stylet essentially serves as an extension cord. In the PNS system, there is no need for the copper lead extension, as the receiver is already close enough to the surface of the skin to receive a signal. In these cases, a “dummy” white plastic stylet is inserted instead. The white plastic stylet serves no medical purpose. Rather, the white plastic stylet is used solely to satisfy the Medicare billing code criteria.

42. As illustrated in Stimwave’s recent LinkedIn post concerning a PNS procedure on a patient’s knee, because of the close proximity to the skin, the location easily suits an antenna over the internal receiver – thus eliminating any medical need for a copper stylet extension:

Verizon LTE

1:04 PM

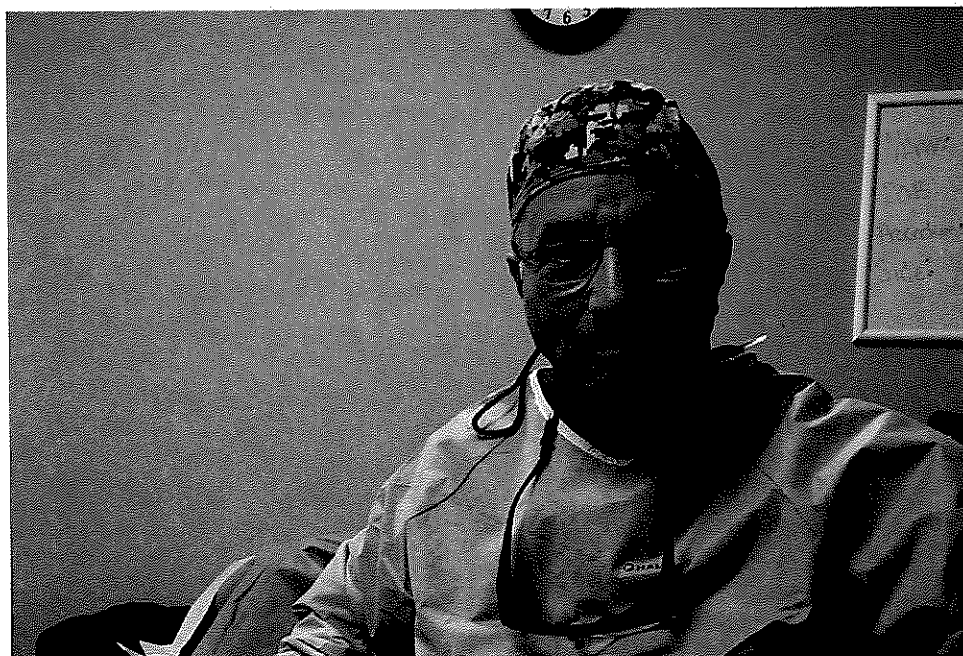
65%

**Sue Petersohn RN, BSN, MBA - Be...**

Clinical Specialist-Pacific Northwest

Congratulations to Dr. Marshall Bedder, M.D., F.R.C.P. (C) for performing the first Stimwave PNS trial in Washington state. Thank you Dr. Bedder!

Stimwave has the first FDA cleared Freedom System™ for Spinal Cord Stimulation, Dorsal Root Ganglion Stimulation, and Peripheral Nerve Stimulation. The Stimwave Stimulator System, with just a single device implanted through a needle, provides a non-surgical therapy option for chronic pain. This system utilizes the world's smallest, wireless, microsize neurostimulator and leverages patented advancements in microtechnology. The Stimwave platform is revolutionizing the industry with sleek, easily wearable options giving patients and clinicians affordable choices for pain management.



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**B. MEDICALLY UNNECESSARY PROCEDURES AND FRAUDULENT BILLING PRACTICES**

43. For Stimwave's PNS device, Stimwave charges physicians as much as \$23,000.

44. In order to induce physicians to use its products and justify the high cost of the device, Stimwave trains physicians to use the Medicare billing reimbursement code 64590 (generator), in addition to the reimbursement code 64555 (lead).

45. Stimwave markets its devices by using reimbursement calculators to show physicians how to maximize their revenues by using Stimwave's devices.

46. As described above, traditional neuromodulation systems use a large generator/battery type device (generally the size of a hockey puck) that is implanted in a subcutaneous "pocket" incision in the patient. The billing code 64590 is used to reimburse physicians for the generator/battery type device. Reimbursement under 64590 was as much as \$17,796 in 2017.

47. Stimwave hosts various medical education and training courses for physicians. These free courses serve the dual purpose of teaching physicians to use Stimwave devices and ensuring that these physicians would use Stimwave products in their surgeries.

48. In order to rationalize the billing of reimbursement code 64590, Stimwave intentionally designed the surgical procedures and trained physicians to implant the PNS device to involve multiple incisions/procedures. According to Stimwave, by including a second incision/procedure to the placement of the receiver stylet, physicians are justified in billing the generator code 64590 – despite the fact that the device does not have a generator/battery type device.

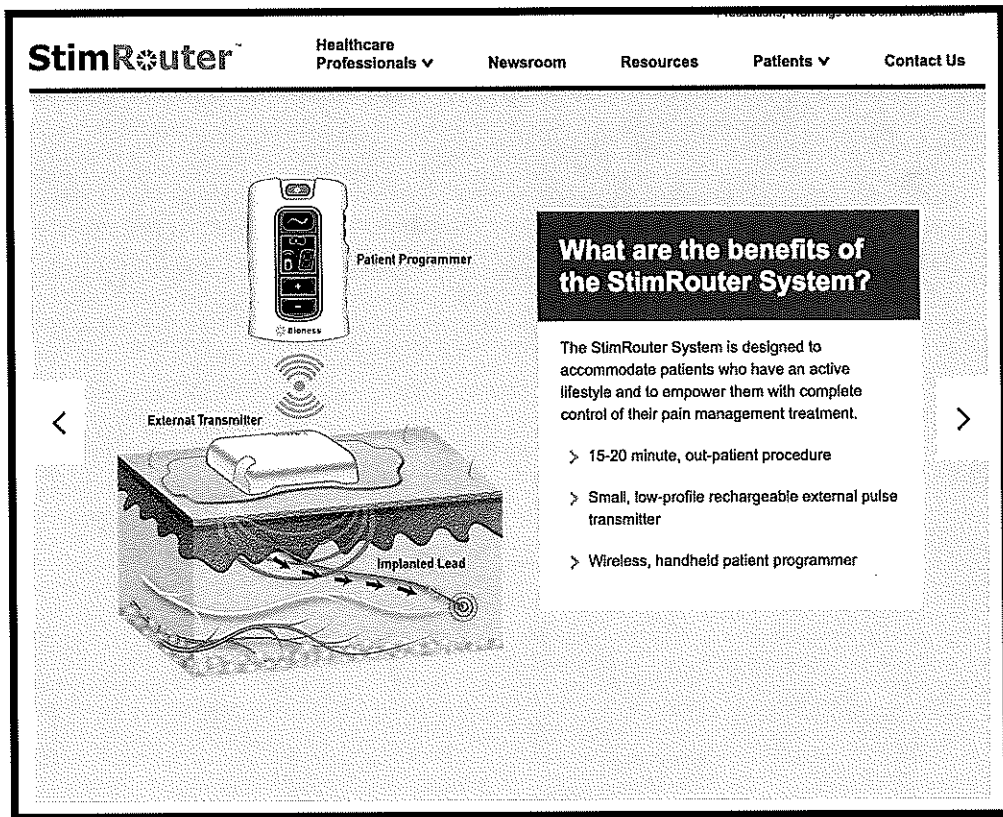
49. The PNS procedures do not require the copper receiver stylet extension. Because the receiver microchip is placed so close to the surface of the skin in a PNS procedure, adding the copper stylet would interfere with the connection between the receiver microchip and the external antenna. Indeed, during the Relator's training, Relator asked why Stimwave did not add the copper receiver stylet to the lead. Chad Andresen explained that adding the copper receiver stylet to the lead can "mess with the wavelength."

50. In order to explain the purpose and reasonableness of the second incision/procedure in PNS procedures, Stimwave designed the white plastic "dummy" stylet to be utilized in order to satisfy the billing requirements for reimbursement code 64590.

51. As depicted in the image below, the first two incisions at the base of the skull in this cranial procedure were connected to the "generator" pocket incision at the base of the neck. In a SCS procedure, the next step in the procedure would be to add the copper receiver stylet to ensure a connection between the receiver microchip and the antenna. But in the PNS procedure, the white plastic "dummy" stylet is used instead. In fact, Michael Baja stated that "we don't need them...." Indeed, there are PNS procedures where Stimwave has advised physicians to simply discard the plastic stylet entirely and not even use it. In these cases, the device can be tied down and secured at the point of the first incision without ever having to make the second incision.

52. By adding the additional incision at the base of the neck, Stimwave-trained physicians are able to use reimbursement code 64590 to recover an additional amount of up to \$17,796.

53. Unlike traditional systems, Stimwave's device is more similar to Bioness's StimRouter (PNS) System – an implantable neuromodulation device to treat chronic peripheral nerve pain:



54. Yet on PNS procedures, physicians using Bioness's device are only able to bill Medicare for a Lead/Electrode Array. Physicians are not able to use the generator billing code 64590 because the device does not use a generator/battery type device. Compare Stimwave's PNS device and Bioness's PNS device's reimbursements:

Product			Bioness		
StimQ			ASC		
Reimbursement			Reimbursement		
Trial			Trial (Block - Level 3 Nerve Injection)		
64555	\$4,507	\$5,743	64414-17, 64430	\$345	\$639
Permanent Implant			Permanent Implant		
64555	\$4,507	\$5,743	64555	\$4,507	\$5,743
64590	\$16,180	\$17,796	64590	NA	NA
L8683	\$5,117.79	\$5,117.79	L8683	NA	NA
	\$30,312	\$34,400		\$4,852	\$6,382
Cost			Cost		
Net to Facility	\$30,312	\$34,400		\$4,852	\$6,382

55. Relator's conversations with other sales representatives, upper management and physicians, revealed that countless others have shared these same concerns. For example, in a conversation between Brian Price, Stimwave's Dallas, Texas sales representatives, and Dr. Richard Weiner, an investor and consultant for Stimwave who instructs and trains physicians who are new to the Stimwave technology during his cadaveric labs, Dr. Weiner told Price that he would not be doing any more PNS implants, due in large part to the uncertainty surrounding reimbursement code 64590. Dr. Weiner explained to Price that he was concerned that, if he does these implants and uses reimbursement code 64590, he may need to pay back the entire Medicare reimbursement associated with the code. Dr. Weiner explained further that he was concerned about whether the product will pass the RAC (Regulatory Affairs Certification Test). In addition, Dr. Weiner told Price that he "does not want to end up on the front page of the newspaper."

56. During a training lab involving the PNS device conducted by another Stimwave physician-consultant, the white plastic "dummy" stylet was discarded entirely as unnecessary and not used in the procedure. By discarding the white plastic "dummy" stylet, the physician discarded the very thing that purportedly justified using billing code 64590.

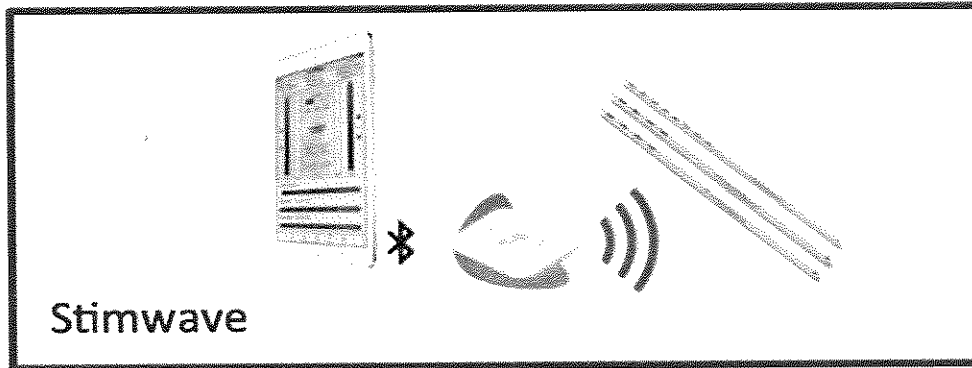
57. Indeed, in September 2017, Patrick Tompkins advised Relator that the purpose of the second incision/procedure for PNS patients when the internal receiver is accessible was to satisfy billing code 64590.

**C. STIMWAVE PROMOTES ITS DEVICES BY TRAINING PHYSICIANS TO INCREASE REIMBURSEMENTS.**

58. Neither Stimwave's SCS device nor its PNS device use a generator that traditional systems use:

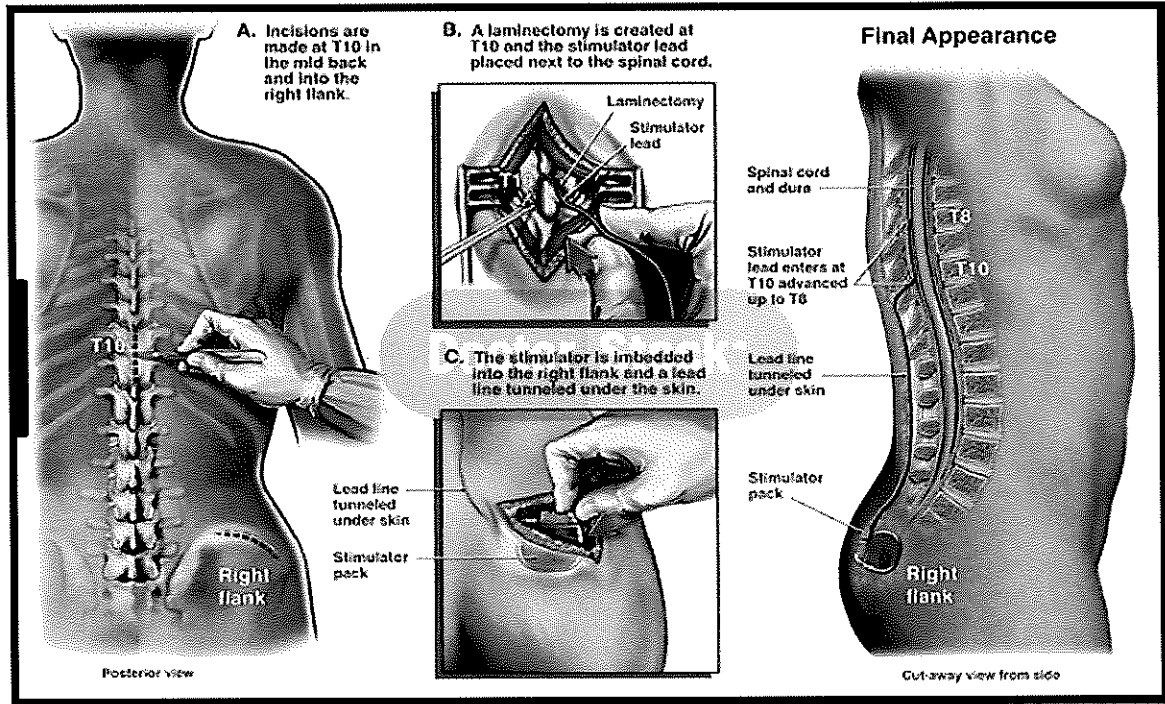


**Figure 3: Different Companies offering therapy, including: Medtronic, St. Jude, Boston Scientific, Nevro, and Stimwave. Medtronic offers therapy that can be MRI compatible, monopolar compatible. St. Jude offers upgradable software, which may be able to accommodate "burst" stimulation in future. Boston Scientific offers the largest paddle's and utilizes "independent current driver" technology. Nevro stimulates at 10,000 hertz, which offers paresthesia free stimulation. All of these technologies require an implanted battery, such as a pacemaker, except for Stimwave, which is wireless. With Stimwave, there is an external system that needs to be close by that will inductively stimulate the internal wire, with no implanted battery.**



59. In both the SCS and PNS procedures, the receiver microchip is contained in the lead which is implanted in the first incision, without the need to create a pocket for the generator. As described above, no additional tunneling system is necessary to bring the

lead to the generator – as is needed with many competitive products (as depicted in the below illustration):



60. Despite this material difference between its products and traditional systems, Stimwave markets the ability of physicians to obtain reimbursement under billing codes expressly for the use of a “generator.”

61. Stimwave is training physicians to use the following billing reimbursement codes for the implant of a generator:

- a. PNS Reimbursement Code: 64590 - \$16,180 (generator/receiver);
- and
- b. SCS Reimbursement Code: 63865 - \$23,148 (generator/receiver)

62. According to Stimwave, despite not using a generator in its medical devices, Medicare is billed separately under the “generator” reimbursement code. Stimwave’s receiver is also incorporated in the device that is implanted in the first incision/procedure.

63. Stimwave knows that this large reimbursement for a quick procedure would drive usage, and it sells it to physicians on this basis. Stimwave knows that selling the reimbursements/gross margins is an effective way to convert physicians to be users of its devices.

**D. STIMWAVE OFFERS INVESTMENT OPPORTUNITIES AND CONSULTING AGREEMENTS TO FREQUENT-USERS OF STIMWAVE DEVICES.**

64. Upon information and belief, Stimwave uses a business model that incentivizes physicians to use Stimwave medical devices by rewarding them with lucrative consulting agreements, investment opportunities in the Defendants’ business, memberships on Stimwave’s boards, and discounted medical devices as an illegal quid pro quo.

65. Stimwave provides physicians with substantial discounts on medical devices in order to incentivize physicians to use its products. All discounts are approved by the Vice President of Sales.

66. Many of Stimwave’s consultants, if not all, are among the most prolific and frequent users of Stimwave devices. For example, Stimwave’s top consultants, Dr. Weiner and Dr. Kloth, who instruct and train physicians who are new to the Stimwave technology, frequently use Stimwave’s products in their own surgeries.

67. In addition to consulting arrangements, Stimwave also offers investment opportunities in Stimwave and membership of Stimwave’s boards. For example, Dr.

Weiner and Dr. Kloth are both investors in Stimwave. Dr. Kloth is also a member of its board.

**E. UNREPORTED ADVERSE EVENTS**

68. Starting in at least the summer of 2017 (if not earlier), Stimwave was made aware of numerous incidents of its medical devices splitting apart inside patients due to defective design and/or manufacturing.

69. Rather than addressing the defects by reporting adverse events to the FDA or proposing to remedy the defect, Stimwave sought to deflect concerns of surgeons and patients and to conceal Stimwave's knowledge of significant rate of failure. Defendants have not reported adverse events related to the use of Stimwave's medical products.

70. By failing to report significant adverse events with the use of Stimwave's medical devices, Defendants caused patients to unnecessarily undergo multiple revisional procedures often requiring general anesthesia.

71. For example, on a June 2017 conference call with the sales team, Elizabeth Greene explained that Stimwave was currently addressing concerns surrounding the manufacturing of its leads with two (2) marker bands (lead B). The leads were assembled as two separate pieces and were disconnecting at the marker band during their removal at the end of patient trials and leaving the distal end of the lead in the patient. Ms. Greene attempted to stifle any concerns around FDA reporting of adverse events and talk surrounding manufacturing of defective leads. Ms. Greene reiterated what was defined as an adverse event and the need to report under the current guidelines. It was brought to her attention that any "adverse events" with other companies were addressed and reported. Ms. Greene was adamant that no reporting was necessary.

72. Stimwave was also made aware of numerous incidents involving lead failure and migration. These hardware-related complications went unreported to the FDA.

73. For example, in late summer 2017, on another conference call with the sales team, Perryman highlighted a number of cases taking place in California at Kaiser Permanente where lead migration was causing a neurosurgeon to explant three (3) or more previously implanted systems by a colleague. Perryman was extremely agitated on the call, blaming the representative for poor instruction on how to anchor the device. These adverse events were not reported to the FDA.

74. Relator is aware, for example, that Dr. Brian Sedrak of Kaiser Permanente has experienced both splitting of the lead and lead migration inside the patient.

**F. DEFENDANTS' ILLEGAL SCHEME VIOLATED FEDERAL LAW**

75. Defendants' illegal scheme has caused numerous false claims to be submitted to federal and state healthcare programs throughout the United States, and constitutes a violation of the Anti-Kickback and Stark statutes. Defendants' misconduct cheated the federal and state governments out of hundreds of thousands of dollars that should not have been paid, thereby illegally enriching the Defendants at taxpayer expense.

76. At all relevant times, Defendants have known that Stimwave's medical devices were being paid for or reimbursed by Government programs, including Medicaid and Medicare Part B. Defendants supervised the kickback scheme and knew that Medicare, Medicaid, and other federal program beneficiaries represent a significant percentage of surgery patients, and that as a result of the kickbacks, doctors across the country had performed spinal surgeries on Medicare and Medicaid patients using Stimwave's medical devices.

77. Approximately eighty percent (80%) of all medical devices approved by the FDA are covered by Medicare. Moreover, Medicare spends more than \$20 billion per year on Implantable Medical Devices (“IMD”) as part of its Part A (hospital insurance) budget, and Part A payments increased 4.3% each year from 2004 to 2009 according to the US Government Accountability Office (cumulatively, a 52% increase since 2002). Medicare Part A payments for IMDs between 2006 and 2014 increased 32.6% alone.

78. Defendants knew, or reasonably should have known, that their conduct described herein would lead to the submission of claims for reimbursement by government programs that were not eligible for reimbursement. But for Defendants’ illegal conduct, reimbursement for the use of Stimwave’s medical device products would not have occurred. As a result, Defendants have caused, and continues to cause, the submission of false claims to government programs, and it has benefited from the payment of those false claims.

79. The fraudulent scheme served its intended purpose, as it has induced physicians to seek reimbursement for surgical procedures involving Stimwave’s medical device products. The government programs did, in fact, reimburse those claims based on Defendants’ illegal scheme.

80. The fraudulent scheme has caused substantial claims for reimbursements of Stimwave’s medical device products to be submitted for reimbursement by Government programs. The Government programs did, in fact, reimburse those claims.

81. At least in part as a result of Defendants’ illegal scheme, Defendants’ medical device products have been heavily used for the treatment of Medicaid, Medicare Part B, Medicare Part D, and other government program participants.

**G. PROVIDER AGREEMENTS AND HOSPITAL COST REPORTS  
SUBMITTED FOR REIMBURSEMENT FROM MEDICARE**

82. In order to establish eligibility for Medicare reimbursement, health care providers and hospitals must sign a mandatory Medicare Enrollment form known as CMS-855 (the “Provider Agreement”). Within the Provider Agreement, the services rendered must be identified by entering the relevant HCPCS code. In signing the Form Provider Agreement, providers and hospitals agree to comply with all Medicare laws, regulations, and program instructions, including the Anti-Kickback Statute, as a precondition of Medicare payment. The certification of compliance with these requirements that is contained in the Provider Agreement and to which health care providers and hospitals attest in signing the form reads:

I agree to abide by the Medicare laws, regulations and program instructions that apply.... The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier’s compliance with all applicable conditions of participation in Medicare.

Form CMS-855A; Form CMS-855I. The Provider Agreement further states that this certification is one of the “requirements that the provider must meet and maintain in order to bill the Medicare program.” Form CMS-855A.

83. Hospitals, but not doctors, must submit a Hospital Cost Report along with their claim for reimbursement for Medicare. 42 U.S.C. § 1395g(a); 42 C.F.R. § 413.20. The Hospital Cost Report includes the following statement:

Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment

under federal law. Furthermore, if services identified in this report provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

Form CMS-2552-10. The person certifying the report is required to sign a statement which reads:

To the best of my knowledge and belief, it [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provisions of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

84. In reimbursing hospitals for operating costs, Medicare pays according to a per-patient standardized rate, called the Diagnostic Related Group (“DRG”) rate. 42 U.S.C. § 1395ww(d)(3)(A), (D). The hospital submits a claim for a surgery by identifying the DRG associated with the surgery. The DRG reimbursement rate is “intended to fairly compensate the hospital for all costs associated with the surgery, including the medical device costs.”

**IV. THE UNITED STATES AND QUI TAM STATES WERE CHEATED OUT OF SUBSTANTIAL SUMS AS A RESULT OF THE FALSE REPORTS INDUCED BY DEFENDANTS’ SCHEME**

85. Because Defendants intended that false reports be submitted to the Government, the Government was wrongfully overcharged for reimbursement of the Company’s medical device products.

86. Defendants knowingly (with actual knowledge of the information, and acting in deliberate ignorance, or reckless disregard, of the truth or falsity of the

information) made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Government.

87. By virtue of the false or fraudulent claims that Defendants knowingly caused to be presented, the United States and the Qui Tam States have suffered actual damages and are entitled to recover treble damages plus a civil monetary penalty for each false claim.

## **V. STATUTORY AND REGULATORY ENVIRONMENT**

### **A. THE FALSE CLAIMS ACT**

88. The federal False Claims Act (“FCA”) was originally enacted during the Civil War, and was substantially amended in 1986 and 2009. Congress enacted these amendments to enhance and modernize the government’s tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the government’s behalf.

89. The FCA imposes liability on any person who “knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval” to an officer or employee of the United States government. 31 U.S.C. § 3729(a)(1)(a) (2008). The statute further imposes liability on a person who (1) uses, or causes to be made or used a false record or statement material to get a false or fraudulent claim paid or approved by the government; (2) conspires to defraud the government by getting a false or fraudulent claim paid or approved by the government, or (3) uses a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government.

Id. at 3729 §§ (a)(1)(b)-(g). To satisfy the statute's knowledge requirement, a person must “(1) ha[ve] actual knowledge of the information; (2) act[] in deliberate ignorance of the truth or falsity of the information; (3) or act[] in reckless disregard of the truth or falsity of the information,” but “no specific intent to defraud” is required. Id. § 3729(b).

90. The FCA does not create a private cause of action, but permits a person, designated a “Relator” to bring a civil action “for the person and for the United States government . . . in the name of the government.” 31 U.S.C. § 3730(b).

91. Liability under these FCA provisions is a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the Government.

92. A “claim” means any request or demand for money or property provided by the Government under one of its programs, such as Medicaid. 31 U.S.C. §§ 3729(b)(2). Claims made to the states are actionable under the FCA if the Government will reimburse the state for any portion of the claim. 31 U.S.C. § 3729(b)(2)(A).

## **B. THE ANTI-KICKBACK STATUTE**

93. The Medicare and Medicaid Patient Protection Act, 42 U.S.C. § 1320a-7b(b) (the “Anti-Kickback Statute” or “AKS”), arose out of a Congressional concern that payoffs to those who influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

94. The Anti-Kickback statute prohibits any person or entity from offering or providing “any remuneration” to induce or reward any person for referring, recommending

or arranging for the purchase of any item for which payment is sought from under any federally-funded health care program, including Medicare, Medicaid, and TRICARE. 42 U.S.C. § 1320a-7b(b). Violation of the statute can subject the perpetrator to criminal and civil penalties, as well as exclusion from participation in federally-funded healthcare programs.

95. The term “remuneration” includes anything of value, in whatever form, whether in cash or in kind, or offered directly or indirectly.

96. Payment of remuneration of any kind violates the statute if one of the purposes of the payment is to induce referrals.

97. Thus, the AKS prohibits medical device manufacturers or suppliers from offering to pay any remuneration, if one of the purposes of the remuneration is to induce physicians or others to recommend or use products paid in whole or in part by federal healthcare programs.

98. Examples of activities prohibited by the AKS include payments for sham consulting services, bogus research and educational grants, travel and lodging expenses, expensive meals and wine, and other gifts and discounts. These activities are especially suspect if the medical device supplier selects the physician based on its belief that the physician is likely to prescribe the company’s products, rather than on the physician’s professional qualifications or services he or she actually rendered to the company.

99. The AKS provides safe harbor provisions for personal service arrangements, 42 C.F.R. § 1001.952(d), which, as discussed above, Defendants does not satisfy.

100. Each of the federally-funded health care programs requires every provider and supplier providing items and services for federal healthcare beneficiaries to promise and ensure compliance with the AKS as a material condition of payment of the resulting claims.

101. A claim “that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim” for purposes of the False Claims Act. 42 U.S.C § 1320a-7b(g).

102. Giving a person the opportunity to earn money for referring patients may constitute an inducement under the AKS.

103. As stated by the Office of Inspector General of the Department of Health & Human Services (“OIG”) with respect to medical device suppliers:

Manufacturers, providers, and suppliers of health care products and services frequently cultivate relationships with physicians in a position to generate business for them through a variety of practices, including gifts, entertainment, and personal services compensation arrangements. These activities have a high potential for fraud and abuse and, historically, have generated a substantial number of anti-kickback convictions. There is no substantive difference between remuneration from a pharmaceutical manufacturer or from a durable medical equipment or other supplier--if the remuneration is intended to generate any federal health care business, it potentially violates the anti-kickback statute.

OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23737 (May 5, 2003).

104. As discussed above, federal health care programs require every provider, hospital, and supplier who provides items and services to federal healthcare beneficiaries to sign Provider/Supplier Agreements, and Hospital Cost Reports, to establish their eligibility to seek reimbursement.

105. The express language of the AKS, the certification of the provider/supplier agreements and hospital cost reports, and the repeated statements of the agency charged with administering the statute establish without question that compliance with the AKS is material to decision to pay claims for federal program beneficiaries.

106. Compliance with the AKS is a material condition of payment under all publicly-funded healthcare programs, including Medicare, Medicaid, CHAMPUS-TRICARE, CHAMPVA, Federal Health Benefit Program, and other federal and state health care programs (hereinafter referred to as “Government healthcare programs”).

### **C. THE STARK STATUTE**

107. The Stark Statute, 42 U.S.C. § 1395nn, prohibits a physician from making referrals for certain “designated health services” payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies. The statute also prohibits the entity from billing Medicare for those referred services. The Center for Medicare and Medicaid (“CMS”) has promulgated regulations interpreting the statute.

108. A financial relationship under the Stark laws includes arrangements involving any remuneration between a physician (or an immediate family member of such physician) and an entity. 42 U.S.C. §§ 1395nn(a)(2)(B), (h)(1)(A).

109. A “referral” includes, among other things, “a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare....” 42 C.F.R. § 411.351. A referring physician is defined as “a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made to another person or entity.” *Id.*

110. Claims submitted in violation of the Stark Statute are ineligible for payment, and violate material conditions of payment of federal healthcare programs.

111. A claim for payment that is based on a violation of the Stark Statute constitutes a false claim under the FCA.

**D. THE PHYSICIANS PAYMENTS SUNSHINE ACT**

112. Regulatory scrutiny of the medical industry has also increased with the enactment of the Physician Payments Sunshine Act and the Patient Protection and Affordable Care Act in 2010. Financial relationships between physicians and medical device companies can create negative influences on physicians' judgment that compromise patient care and jeopardize the public's trust. In response to these concerns, when Congress passed the Sunshine Act in March 2010, it seized the opportunity to mandate greater transparency regarding these financial relationships by including the Sunshine Act.

113. These laws broaden the scope of the Anti-Kickback Statute and False Claims Act and require companies to report all transfers of value to physicians to the U.S. Department of Health and Human Services on an annual basis beginning August 1, 2013. It is applicable to manufacturers of prescription drugs, devices, biologicals and medical supplies requiring pre-market approval or notification and products covered under Medicare, Medicaid or the Children's Health Insurance Program ("CHIP").

114. Specifically, the Physician Payments Sunshine Act ("PPSA" or "Sunshine Act")—also known as section 6002 of the Affordable Care Act (ACA) of 2010—requires medical device manufacturers to disclose to CMS any payments or other transfers of value made to physicians or teaching hospitals. 42 C.F.R. § 403.904. It also requires certain manufacturers and group purchasing organizations (GPOs) to disclose any physician ownership or investment interests held in those companies. 42 C.F.R. § 402.906. Another

broad category of reporting covers research payments. This includes any payment made for participation in preclinical research, clinical trials, or other product development activities. 42 C.F.R. § 403.904(f).

115. As a whole, the Sunshine Act seeks to help make financial relationships clearer by providing a central location for financial interactions to be reported and monitored. Furthermore, it is meant to discourage “dishonest influence on research, education, and clinical decision-making.”

116. Unlike other state and federal laws governing the health care industry, the Sunshine Act depends on self-reporting instead of relying on whistleblowers and government investigators. In particular, the program requires “applicable manufacturers” and “applicable GPOs,” collectively deemed “Reporting Entities,” to report to CMS any payment or transfers of value made to physicians and teaching hospitals. Applicable manufacturers, such as medical device manufacturers, are required to report all payments falling into the following categories:

consulting fees, compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program, [h]onoraria, [g]ifts, [e]ntertainment, [f]ood and beverage, [t]ravel and lodging, [e]ducation, [r]esearch, [c]haritable contributions, [r]oyalty or [l]icense, [c]urrent or prospective ownership or investment interest, [c]ompensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program, [c]ompensation for serving as faculty or as a speaker for an accredited or certified continuing education program, [g]rants, [and] [s]pace rental or facility fees (teaching hospital only).

78 Fed. Reg. 9457, 9477-9481 (February 8, 2013): 42 CFR 402 (as specified by Pub. L. No. 111-148 § 6002, (2010) (codified at 42 U.S.C.A § 1128G(a)(1)(A)(vi) (West Supp. 2011)).

117. Sunshine Act penalties are severe and include civil monetary penalties of up to \$10,000 for each item not reported. There is an annual maximum of \$150,000 with respect to each annual submission. If a company knowingly fails to accurately and completely report a payment or ownership interest, the penalty is up to \$100,000 for each item with an annual maximum of one million dollars. 42 C.F.R. § 912.

## **VI. REIMBURSEMENT BY GOVERNMENT-FUNDED HEALTH CARE PROGRAMS**

118. The Health Insurance for the Aged and Disabled Program, popularly known as Medicare, was created in 1965 as part of the Social Security Act (SSA). The Secretary of Health and Human Services (“HHS”) administers the Medicare Program through the Centers for Medicare and Medicaid Studies (“CMS”), a component of HHS.

119. The Medicare program consists of two primary parts. Medicare Part A authorizes the payment of federal funds for hospitalization and post-hospitalization care. 42 U.S.C. §§ 1395c to 1395i-5. Medicare Part B is a federally subsidized, voluntary insurance program that covers a percentage of the fee schedule for physician services as well as a variety of other “medical and other services.” 42 U.S.C. §§ 1395j to 1395w-5.

120. The Medicaid program was also created in 1965 as part of the Social Security Act, which authorized federal grants to states for medical assistance to low-income persons, blind, disabled, or members of families with dependent children or qualified pregnant women or children. The Medicaid program is jointly financed by the federal and state governments. CMS administers Medicaid on the federal level. Within broad federal rules, each state decides eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. The states directly pay providers, with the states obtaining the federal share of the payment from accounts which

draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994). The federal share of each state's Medicaid expenditures varies by state.

121. Various other federally-funded medical coverage programs exist to help discrete populations of enrollees obtain medical care, including the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), TRICARE, and the Veterans Administration, among others.

122. Reimbursement practices under all federally-funded healthcare programs closely align with the rules and regulations governing Medicare reimbursement.

123. Reimbursement for Medicare claims is made by the United States through CMS which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS. 42 C.F.R. § 421.5(b) (1994).

124. To participate in the Medicare Program, a health care provider must file a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. The provider agreement requires compliance with the requirements that the Secretary deems necessary for participation in the Medicare Program and in order to receive reimbursement from Medicare. The provider agreement specifically requires compliance with the federal Anti-Kickback Statute. 42 U.S.C. § 1320a-7b(b).

#### **A. MEDICARE PART A**

125. Part A of the Medicare program authorizes payment for institutional care, including hospitalization, for eligible patients.

126. Under Medicare Part A, hospitals enter into an agreement with Medicare to provide health items and services to treat Medicare patients. The hospital, also called a "provider," is authorized to bill Medicare for that treatment.

127. During the relevant time period, CMS reimbursed hospitals for inpatient Part A services through Medicare Administrative Contractors (“MACs”).

128. MACs are private insurance companies that are responsible for determining the amount of payments to be made to providers. See 71 Fed. Reg. 67960, 68181 (Nov. 24, 2006). Under their contracts with CMS, MACs review, approve, and pay Medicare bills, called “claims,” received from hospitals. See 42 C.F.R. § 421.5(b).

129. Since 2007, in order to get paid, Hospitals must submit claims for payment on Form CMS-1450, also called Form UB-04. This form contains patient-specific information including the diagnosis and type of services that are assigned or provided to the Medicare patient. The Medicare program relies upon the accuracy and truthfulness of the UB-04 Forms to determine whether the service is payable and what amounts the hospital is owed.

130. In addition, and at the end of every fiscal year, as a prerequisite to payment, CMS requires hospitals to submit to the MACs a form CMS-2552, commonly known as the hospital “cost report.” 42 U.S.C. § 1395g(a); 42 C.F.R. § 413.20. The cost report identifies any outstanding costs that the hospital is claiming for reimbursement that year. It serves as the final claim for payment that is submitted to Medicare. The Medicare program relies upon the accuracy and truthfulness of the cost report to determine what amounts, if any, the hospital is owed, or what amounts the hospital has been overpaid during the year.

131. In 1983, Congress established the prospective payment system (“PPS”) as the system by which hospitals are reimbursed for inpatient hospital costs. Under PPS, the amount Medicare pays a hospital for treating an inpatient Medicare beneficiary is based in

large part on the particular condition that led to the patient's admission to, or that was principally treated by, the hospital.

132. Under PPS, a patient's illness or condition is categorized under a classification system called a diagnostic related group ("DRG"). The DRG establishes how much the hospital will be paid under Medicare and reflects the resources the patient's condition or treatment typically requires. The MACs uses the patient specific information (for example, the diagnosis codes) submitted by the hospital on the UB-04 to determine what DRG is assigned to a certain claim, and hence, what amount will be paid.

133. The DRG is intended to reimburse the hospital for the expected costs of any items that it must purchase in connection with the hospitalization. The DRG is intended to compensate the hospital for any spinal implants, where those devices are appropriately used to treat a Medicare beneficiary.

#### **B. MEDICARE PART B**

134. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and by contributions from the Federal Treasury. Eligible individuals who are 65 or older, or disabled, may enroll in Medicare Part B to obtain benefits in return for payments of monthly premiums. Payments under Medicare Part B are typically made directly under assignment to service providers and practitioners, such as physicians, rather than to the patient/beneficiary. In that case, the physician bills the Medicare Program directly.

135. The United States provides reimbursement for Medicare Part B claims from the Medicare Trust Fund through CMS. To assist in the administration of the Medicare Part B Program, CMS contracts with MACs. 42 U.S.C. § 1395u. MACs are responsible for processing the payment of Medicare Part B claims to providers on behalf of CMS.

136. Medicare reimburses physicians for their professional services under Part B of the program, pursuant to a Physician Fee Schedule (“PFS”). 42 C.F.R. § 414.58(a). Physician fees under the PFS are determined according to a standardized coding system assigned to procedures set forth in the Health Care Financing Administration’s Common Procedure Coding System (HCPCS).

137. Under the HCPCS, the standardized codes called CPT codes are maintained by the American Medical Association, and the CPT code set was adopted by CMS for the reporting of services under Part B of the Medicare program. The CPT code set accurately describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes.

138. The CPT code assigned to a medical procedure determines the payment amount to the physician under Part B. The payment amount for each service paid under the Physician Fee Schedule (“PFS”) is “the product of three factors--(1) a nationally uniform relative value for the service; (2) a geographic adjustment factor for each physician fee schedule area; and (3) a nationally uniform conversion factor (CF) for the service.” Final Rule, 68 Fed. Reg. 63195, 63198 (November 7, 2003). For each physician service, there are three relative values: for physician work; for practice expense; and for malpractice expense. *Id.* These are referred to as Relative Value Units (“RVU’s”). The work RVU’s are based on national valuations of physician time expended for a particular service, and can be accessed on CMS’s website in published schedules.

139. Thus, the DRG system establishes standardized payments for Part B (inpatient) services, and the CPT system established a standardized payment amount for physician services, based on evaluation of the actual average costs of performing that procedure, by region and type of provider, as reported by providers annually.

140. Physicians submit claims for their professional services to Part B of the program on Form CMS-1500.

**C. REIMBURSEMENT FOR SURGERIES USING THE MEDICAL DEVICES AT ISSUE**

141. Costs associated with spine surgery utilizing medical devices are separately billed by the hospitals and surgeons to payors, including Medicare, Medicaid, and TRICARE.

142. Hospitals submit claims to federal programs for the inpatient costs associated with the surgeries, including the cost of the medical devices, on interim claims forms called Forms CMS-1450 (formerly UB-92's) and hospital cost report forms (the final claim). Hospital claims identify the DRG associated with the surgery, which CMS uses to determine the payment amount to the hospital, to include payment for the medical devices used during the surgery.

143. DRG codes are calculated in a manner intended to fairly compensate the hospital for all the costs associated with the surgery, including the medical device costs. DRG rates are recalculated annually based on, among other things, actual claims data.

144. The surgeon performing the surgical procedure separately bills for his or her professional services on Form CMS-1500, identifying the surgical procedure by the appropriate CPT code.

145. Each surgeon chooses which manufacturer's spine hardware to use in each surgery. However, the devices utilized in a spinal surgery are generally purchased by the hospital from the manufacturer.

146. The surgical devices used in spinal surgery include various products that are used to stabilize an injured or degenerating spine. Products used in cervical spinal surgery (neck) include anterior cervical plates and screws, lateral mass screws and rods, laminoplasty plates and screws and bone products, such as bone spacers or cellular bone matrix. Products used in lumbar spinal surgery (lower back) generally consist of pedicle screws and rods, interbody devices such as peek spacers, or corpectomy devices such as mesh spacers, anterior buttress plates and some bone products such as bone spacers and cellular bone matrix.

**D. COMPLIANCE WITH THE AKS AND THE SUNSHINE ACT IS A CONDITION OF PAYMENT**

147. Compliance with the Anti-kickback Statute and the Sunshine Act is a condition of payment for federally-funded healthcare programs, including Medicare, Medicaid, and TRICARE, meaning that if a provider tells CMS or its agent that it provided services in violation of the Anti-kickback Statute or the Sunshine Act, CMS will not pay the claim.

148. Hospitals and physicians enter into a Provider Agreement with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which the hospitals and physicians may not seek reimbursement from federal health care programs, the provider must sign the following certification:

I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws,

regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Form CMS-855A; Form CMS-855I.

149. When a hospital submits a claim for payment, it does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the Anti-kickback Statute and the Sunshine Act.

150. When a physician submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the Anti-kickback Statute and the Sunshine Act.

151. Every Hospital Cost Report also contains a Certification which must be signed by the chief administrator of the provider or a responsible designee of the administrator.

152. The CMS Form 2552-10 Hospital Cost Report certification page includes the following statement:

Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

153. The cost-report certifier is also required to certify that:

To the best of my knowledge and belief, this [Hospital Cost Report] and statement are a true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provisions of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

154. Thus, by signing CMS Form 2552, a hospital provider is required to and does certify that its cost report was (1) truthful, i.e., that the cost information contained in the report is true and accurate; (2) correct, i.e., that it is entitled to reimbursement for the reported costs in accordance with applicable instructions; (3) complete, i.e., that the cost report is based upon all information known to the provider; (4) did not include any services that resulted from an illegal kickback; and (5) the services provided in the cost report were billed in compliance with all provisions of the Stark laws.

155. As a result of the systematic payment of kickbacks to physicians made with the intent and effect of inducing them to use its spinal surgery products, and Defendants' violations of the Sunshine Act, Defendants caused hospitals to submit claims in violation of conditions of payment and claims with false certifications to the United States. Claims submitted as a result of illegally-induced surgeries were false claims.

**VII. DEFENDANTS VIOLATED THE FALSE CLAIMS ACT BY KNOWINGLY CAUSING THE SUBMISSION OF FALSE OR FRAUDULENT CLAIMS OR STATEMENTS**

156. As a party to a Medicaid Rebate Agreement with the United States Secretary of Health and Human Services pursuant to the Social Security Act, Defendants' medical device products and surgical procedures involving such products are only eligible for

reimbursement if and when Defendants are in compliance with applicable federal and state laws.

157. These laws include, but are not limited to, the federal and corresponding state anti-kickback statutes, the FDMA, the Food, Drug & Cosmetic Act and all related regulations, HIPAA, and the Sunshine Act. As described in this Complaint, Defendants have been and continue to be in violation of the aforementioned laws.

158. As described in this Complaint, Defendants have knowingly and repeatedly violated these laws in connection with the use and sale of its medical device products. These violations have not been incidental, but instead have been central to the Defendants' sales strategy.

159. Accordingly, Defendants have knowingly caused the false or fraudulent certification of compliance with these federal and state statutes and regulations.

160. The submission of false or fraudulent certifications of compliance with these statutes and regulations were material to Government programs' decisions to make reimbursements for Stimwave's medical device products. Had Government programs known that the certifications of compliance with the law were false, they would not have made reimbursements for their medical devices.

161. Defendants knowingly causing the submission of false certifications of compliance with the law constituted the making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, and this directly caused Government programs to pay or reimburse for medical device products that were not eligible for payment or reimbursement.

162. Defendants knew that the certifications of compliance with the law that they knowingly caused to be submitted were false, and that the false certifications would cause Government programs to make payments for its drugs.

163. Stimwave's false certifications that Defendants knowingly caused to be submitted have directly caused Government programs to pay or reimburse for medical device products not eligible for payment or reimbursement.

**Count I**  
**(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1);**  
**31 U.S.C. § 3729(a)(1)(A))**

164. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

165. Defendants knowingly caused to be presented, and may still be knowingly causing to be presented, to the Government false or fraudulent claims for payment or approval, in violation of 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3729(a)(1)(A).

166. As a result of Defendants' actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

**Count II**  
**(Violation of False Claims Act, 31 U.S.C. § 3729(a)(2);**  
**31 U.S.C. § 3729(a)(1)(B))**

167. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

168. Defendants knowingly caused to be made or used, and may still be made or used, false or fraudulent records or statements material to the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B).

169. The United States, unaware of the falsity of the claims and/or statements made by Stimwave, its physician-consultants, and certain hospitals, and in reliance on the accuracy of these claims and/or statements, paid and may continue to be paying or reimbursing for the Company's medical device products used in surgical procedures for patients enrolled in Federal Programs.

170. As a result of Defendants' actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

**Count III**  
**(Violation of False Claims Act, 31 U.S.C. § 3729(a)(3);**  
**31 U.S.C. § 3729(a)(1)(C))**

171. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

172. As detailed above, Defendants knowingly conspired, and may still be conspiring, with health care professionals identified and described herein to commit acts, in violation of 31 U.S.C. §§ 3729(a)(1) & (a)(2); 31 U.S.C. §§ 3729(a)(1)(A) & (a)(1)(B). Defendants and these health care professionals committed overt acts in furtherance of the conspiracy as described above.

173. As a result of Defendants' actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

**Count IV**  
**(Violation of Colorado Medicaid False Claims Act)**

174. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

175. This is a civil action brought by Relator, on behalf of the State of Colorado, against Defendants under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-306(2).

176. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly caused to be presented, and may still be causing to be presented, to an officer or employee of the State of Colorado, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(a).

177. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Colo. Rev. Stat. § 25.5-4-305(b).

178. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Colorado, or its political subdivisions, in violation of Colo. Rev. Stat. § 25.5-4-305(f).

179. The State of Colorado, or its political subdivisions, unaware of the falsity of the claims and/or statements knowingly caused to be made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay,

for Stimwave's medical device products for recipients of state and state subdivision funded health insurance programs.

180. As a result of Defendants' actions as set forth above, the State of Colorado and/or its political subdivisions have been, and may continue to be, severely damaged.

**Count V**  
**(Violation of Connecticut False Claims Act)**

181. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

182. This is a civil action brought by Relator, on behalf of the State of Connecticut, against Defendants under the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. § 4-277.

183. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Connecticut, or its political subdivisions, false or fraudulent claims for payment or approval under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 4-275(a)(1).

184. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to secure the payment or approval by the State of Connecticut, or its political subdivisions, false or fraudulent claims under a

medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 4-275(a)(2).

185. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Connecticut, or its political subdivisions, under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 4-275(a)(7).

186. The State of Connecticut, or its political subdivisions, unaware of the falsity of the claims and/or statements knowingly caused to be made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for Stimwave's medical device products for recipients of state and state subdivision funded health insurance programs.

187. As a result of Defendants' actions as set forth above, the State of Connecticut and/or its political subdivisions have been, and may continue to be, severely damaged.

**Count VI**  
**(Violation of District of Columbia False Claims Act)**

188. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

189. This is a civil action brought by Relator, on behalf of the District of Columbia, against Defendants under the District of Columbia False Claims Act, D.C. Code § 2-381.03(b)(1)).

190. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the District of Columbia, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of D.C. Code § 2-381-02(a)(1)).

191. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly used or caused to be used, and may continue to use or cause to be used, false records or statements to get false claims paid or approved by the District of Columbia, or its political subdivisions, in violation of D.C. Code § 2-381.02(a)(2).

192. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly made or used, or caused to be made or used, and may still be making or using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District of Columbia, or its political subdivisions, in violation of D.C. Code § 2-381.02(a)(7).

193. The District of Columbia, or its political subdivisions, unaware of the falsity of the claims and/or statements knowingly caused to be made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for Stimwave's medical device products for recipients of health insurance programs funded by the District of Columbia.

194. As a result of Defendants' actions, as set forth above, the District of Columbia and/or its political subdivisions have been, and may continue to be, severely damaged.

**Count VII**  
**(Violation of Florida False Claims Act)**

195. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

196. This is a civil action brought by Relator, on behalf of the State of Florida, against Defendants under the Florida False Claims Act, Fla. Stat. § 68.083(2).

197. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Florida, or its agencies, false or fraudulent claims for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

198. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida, or its agencies, in violation of Fla. Stat. § 68.082(2)(b).

199. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an

obligation to pay or transmit money to the State of Florida, or its agencies, in violation of Fla. Stat. § 68.082(2)(g).

200. The State of Florida, or its agencies, unaware of the falsity of the claims and/or statements knowingly caused to be made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for Stimwave's medical device products for recipients of health insurance plans funded by the State of Florida or its agencies.

201. As a result of Defendants' actions, as set forth above, the State of Florida and/or its agencies have been, and may continue to be, severely damaged.

**Count VIII**  
**(Violation of Illinois False Claims Whistleblower Reward and Protection Act)**

202. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

203. This is a civil action brought by Relator, on behalf of the State of Illinois, against Defendants under the Illinois False Claims Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175/4(b).

204. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Illinois, or a member of the Illinois National Guard, false or fraudulent claims for payment or approval, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(A).

205. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the

information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false record or statements material to get false or fraudulent claims paid or approved by the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(B).

206. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to conceal, avoid or decrease an obligation to pay or transmit money to the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(G).

207. The State of Illinois, or its political subdivisions, unaware of the falsity of the claims and/or statements knowingly caused to be made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for Stimwave's medical device products for recipients of state funded health insurance programs.

208. As a result of Defendants' actions, as set forth above, the State of Illinois and/or its political subdivisions have been, and may continue to be, severely damaged.

**Count IX**  
**(Violation of Indiana False Claims and Whistleblower Protection Act)**

209. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

210. This is a civil action brought by Relator, on behalf of the State of Indiana, against Defendants under the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-4(a).

211. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented, and may still be presenting or causing to be presented, false claims to the State of Indiana, or its political subdivisions, for payment or approval, in violation of Ind. Code § 5-11-5.5-2(b)(1).

212. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain payment or approval of false claims from the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(2).

213. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to avoid an obligation to pay or transmit money to the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(6).

214. The State of Indiana, or its political subdivisions, unaware of the falsity of the claims and/or statements knowingly caused to be made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for Stimwave's medical device products for recipients of state funded health insurance programs.

215. As a result of Defendants' actions, as set forth above, the State of Indiana and/or its political subdivisions have been, and may continue to be, severely damaged.

**Count X**  
**(Violation of Maryland False Health Claims Act)**

216. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

217. This is a civil action brought by Relator, on behalf of the State of Maryland, against Defendants under the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-Gen. § 2-604.

218. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(1).

219. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(2).

220. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or

decrease an obligation to pay or transmit money to the State of Maryland, or its political subdivisions, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(8).

221. The State of Maryland, or its political subdivisions, unaware of the falsity of the claims and/or statements knowingly caused to be made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid for Stimwave's medical device products for recipients of health insurance programs funded by the state or its political subdivisions.

222. As a result of Defendants' actions, as set forth above, the State of Maryland and/or its political subdivisions have been, and may continue to be, severely damaged.

**Count XI**  
**(Violation of Massachusetts False Claims Act)**

223. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

224. This is a civil action brought by Relator, on behalf of the Commonwealth of Massachusetts, against Defendants under the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12 § 5C(2).

225. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Mass. Gen. Laws ch. 12 § 5B(a)(1).

226. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making,

using or causing to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(a)(2).

227. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(a)(8).

228. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements knowingly caused to be made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for Stimwave's medical device products for recipients of health insurance programs funded by the state or its political subdivisions.

229. As a result of Defendants' actions, as set forth above, the Commonwealth of Massachusetts and/or its political subdivisions have been, and may continue to be, severely damaged.

**Count XII**  
**(Violation of New Jersey False Claims Act)**

230. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

231. This is a civil action brought by Relator, on behalf of the State of New Jersey, against Defendants pursuant to the New Jersey Fraud False Claims Act, N.J. Stat. Ann. § 2A:32C-5(b).

232. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly or intentionally presented or caused to be presented, and may still be presenting or causing to be presented, to an employee, officer or agent of the State of New Jersey, or to any contractor, grantee, or other recipient of State funds, false or fraudulent claims for payment or approval, in violation of N.J. Stat. Ann. § 2A:32C-3(a).

233. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(b).

234. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(g).

235. The State of New Jersey, or its political subdivisions, unaware of the falsity of the claims and/or statements knowingly caused to be made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for Stimwave's medical device products for recipients of health insurance programs funded by the state or its political.

236. As a result of Defendants' actions, as set forth above, the State of New Jersey and/or its political subdivisions have been, and may continue to be, severely damaged.

**Count XIII**  
**(Violation of New York False Claims Act)**

237. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

238. This is a civil action brought by Relator, on behalf of the State of New York, against Defendants under the New York False Claims Act, N.Y. State Fin. Law § 190.

239. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer, employee or agent of the State of New York, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of N.Y. State Fin. Law § 189(1)(a).

240. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved by the State of New York, or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(b).

241. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making,

using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New York, or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(g).

242. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements knowingly caused to be made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for Stimwave's medical device products for recipients of health insurance programs funded by the state or its political subdivisions.

243. As to the New York Medicaid program, the state's regulatory regime provides that an "overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake." N.Y. Comp. Codes R. & Regs. tit. 18, § 518.1(c). The regime defines "unacceptable practice," to include "[b]ribes and kickbacks," id. § 515.2(b)(5), and lists within this category both "soliciting or receiving," id. § 515.2(b)(5)(ii), and "offering or paying," id. § 515.2(b)(5)(iv), "either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program," id. § 515.2(b)(5)(ii), (iv). New York's anti-kickback statute forbids kickbacks in similar terms. See N.Y. Soc. Serv. Law §§ 366–d, –f.

244. As a result of Defendants' actions, set forth above, the State of New York and/or its political subdivisions have been, and may continue to be, severely damaged.

**Count XIV**  
**(Violation of Oklahoma Medicaid False Claims Act)**

245. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

246. This is a civil action brought by Relator, on behalf of the State of Oklahoma, against Defendants pursuant to the Oklahoma Medicaid Fraud False Claims Act, Okla. Stat. tit. 63, § 5053.2(B)(1).

247. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Oklahoma, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Okla. Stat. tit. 63, § 5053.1(B)(1).

248. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(2).

249. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or

decrease an obligation to pay or transmit money to the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(7).

250. The State of Oklahoma, or its political subdivisions, unaware of the falsity of the claims and/or statements knowingly caused to be made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for Stimwave's medical device products for recipients of Medicaid.

251. As a result of Defendant's actions, as set forth above, the State of Oklahoma and/or its political subdivisions have been, and may continue to be, severely damaged.

**Count XV**  
**(Violation of Texas Medicaid Fraud Prevention Act)**

252. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

253. This is a civil action brought by Relator, on behalf of the State of Texas against, Defendants under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.101(a).

254. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false statements or misrepresentations of material fact that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the benefit or payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(1).

255. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information,

knowingly concealed or failed to disclose, or caused to be concealed or not disclosed — and may still be concealing or failing to disclose, or causing to be concealed or not disclosed — information that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(2).

256. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly made, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, the making of false statements or misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program, in violation of Tex. Hum. Res. Code Ann. § 36.002(4)(B).

257. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly made, and may still be making, claims under the Medicaid program for services or products that were inappropriate, in violation of Tex. Hum. Res. Code Ann. § 36.002(7)(C).

258. The State of Texas, or its political subdivisions, unaware of the falsity of the claims and/or statements knowingly caused to be made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for Stimwave's medical device products for recipients of Medicaid.

259. As a result of Defendants' actions, as set forth above, the State of Texas and/or its political subdivisions have been, and may continue to be, severely damaged.

**Count XVI**  
**(Violation of Virginia Fraud Against Taxpayers Act)**

260. Relator incorporate herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

261. This is a civil action brought by Relator, on behalf of the Commonwealth of Virginia, against Defendants under the Commonwealth of Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.5(A).

262. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

263. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Va. Code Ann. § 8.01-216.3(A)(2).

264. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(7).

265. The Commonwealth of Virginia, or its political subdivisions, unaware of the falsity of the claims and/or statements made, or knowingly caused to be made, by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for Stimwave's medical device products for recipients of state funded health insurance programs.

266. As a result of Defendants' actions, as set forth above, the Commonwealth of Virginia and/or its political subdivisions have been, and may continue to be, severely damaged.

**Count XVII**  
**(Violation of California False Claims Act)**

267. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

268. This is a civil action brought by Relator, on behalf of the State of California, against Defendants under the California's False Claims Act, codified at California Government Code sections 12650 through 12656.

269. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Cal. Gov't Code §§ 12650-12656.

270. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the information, knowingly made, used, or caused to be made or used, and may still be making, using or

causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Cal. Gov't Code §§ 12650-12656.

271. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, and with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Virginia, or its political subdivisions, in violation of Cal. Gov't Code §§ 12650-12656.

272. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made, or knowingly caused to be made, by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for Stimwave's medical device products for recipients of state funded health insurance programs.

273. As a result of Defendants' actions, as set forth above, the State of California and/or its political subdivisions have been, and may continue to be, severely damaged.

WHEREFORE, Relator prays for judgment against Defendants as follows:

(a) That Defendants be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. § 3729 et seq.; Colo. Rev. Stat. § 25.5-4-304 et seq.; Conn. Gen. Stat. § 4-274 et seq.; D.C. Code § 2-381.01 et seq.; Fla. Stat. § 68.081 et seq.; Ga. Code Ann. § 49-4-168 et seq.; 740 Ill. Comp. Stat. § 175/1 et seq.; Ind. Code § 5-11-5.5 et seq.; Md. Code Ann., Health-Gen. § 2-601 et seq.; Mass. Gen. Laws ch. 12, § 5A et seq.; N.J. Stat. Ann. § 2A:32C-1 et seq.; N.M. Stat. Ann. § 27-14-1 et seq.; N.Y. State Fin. Law § 187 et seq.; N.C. Gen. Stat. § 1-605 et seq.; Okla. Stat. tit. 63, § 5053

et seq.; Tex. Hum. Res. Code Ann. § 36.001 et seq.; Va. Code Ann. § 8.01-216.1 et seq.; and Cal. Gov't Code § 12650 et seq.

(b) That judgment be entered in Relator's favor and against Defendants in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than \$11,181 or more than \$22,363 per claim as provided by 31 U.S.C. § 3729(a) and adjusted for inflation, to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(c) That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in Cal. Gov't Code § 12651(a)(1), (a)(2)-(3), and (a)(7), plus a civil penalty of not less than five thousand five hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) as provided by Cal. Gov't Code § 12651(a) and adjusted for inflation, to the extent such multiplied penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery.

(d) That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Colorado or its political subdivisions multiplied as provided for in Colo. Rev. Stat. § 25.5-4-305(1), plus a civil penalty of not less than \$11,181 or more than \$22,363 for each act as provided by Colo. Rev. Stat. § 25.5-4-305(1) and adjusted for inflation, to the extent such multiplied penalties shall fairly

compensate the State of Colorado or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(e) That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Connecticut multiplied as provided for in Conn. Gen. Stat. § 4-275(b)(2), plus a civil penalty of not less than \$11,181 or more than \$22,363 for each act in violation of the State of Connecticut False Claims Act, as provided by Conn. Gen. Stat. § 4-275(b)(1) and adjusted for inflation, to the extent such multiplied penalties shall fairly compensate the State of Connecticut for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(f) That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. Code § 2-381.02, plus a civil penalty of not less than five thousand five hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) for each false claim, and the costs of this civil action brought to recover such penalty and damages, as provided by D.C. Code § 2-381.02(a), to the extent such multiplied penalties shall fairly compensate the District of Columbia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(g) That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in Fla. Stat. § 68.082(2), plus a civil penalty of not less than five thousand

five hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) for each false claim as provided by Fla. Stat. Ann. § 68.082(2), to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(h) That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 Ill. Comp. Stat. § 175/3(a)(1), plus a civil penalty of not less than \$11,181 or more than \$22,363 as provided by 740 Ill. Comp. Stat. § 175/3(a)(1) and adjusted for inflation, and the costs of this civil action as provided by 740 Ill. Comp. Stat. § 175/3(a)(2), to the extent such penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(i) That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Indiana, multiplied as provided for in Ind. Code § 5-11-5.5-2(b), plus a civil penalty of at least five thousand dollars (\$5,000) as provided by Ind. Code § 5-11-5.5-2(b), and the costs of this civil action as provided by Ind. Code § 5-11-5.5-2(b), to the extent such penalties shall fairly compensate the State of Indiana for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(j) That judgment be entered in Relator's favor and against Defendants for restitution to the State of Maryland or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful

acts, as provided for in Md. Code Ann., Health-Gen. § 2-602(a), multiplied as provided for in Md. Code Ann., Health-Gen. § 2-602(b)(1)(ii), plus a civil penalty of not more than ten thousand dollars (\$10,000) for each false claim, pursuant to Md. Code Ann., Health-Gen. § 2-602(b)(1)(i), to the extent such penalties fairly compensate the State of Maryland or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(k) That judgment be entered in Relator's favor and against Defendants for restitution to the Commonwealth of Massachusetts or its political subdivisions in the amount of a civil penalty of not less than \$11,181 or more than \$22,363, plus three times the amount of damages, including consequential damages, sustained by Massachusetts as the result of Defendants' actions, plus the expenses of the civil action brought to recover such penalties and damages, as provided by Mass. Gen. Laws ch. 12. § 5B(a) and adjusted for inflation, to the extent such penalties shall fairly compensate the Commonwealth of Massachusetts or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(l) That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of New Jersey or its political subdivisions multiplied as provided for in N.J. Stat. Ann. § 2A:32C-3, plus a civil penalty of not less than \$11,181 or more than \$22,363 as allowed under the federal False Claims Act (31 U.S.C. § 3729 et seq.) for each false or fraudulent claim, to the extent such multiplied penalties shall fairly compensate the State of New Jersey or its political

subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(m) That judgment be entered in Relator's favor and against Defendants for restitution to the State of New York or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.Y. State Fin. Law § 189(1), multiplied as provided for in N.Y. State Fin. Law § 189(1), plus a civil penalty of not less than six thousand dollars (\$6,000) or more than twelve thousand dollars (\$12,000) for each false claim, pursuant to N.Y. State Fin. Law § 189(1), to the extent such multiplied penalties shall fairly compensate the State of New York or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(n) That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Oklahoma or its political subdivisions multiplied as provided for in Okla. Stat. tit. 63, § 5053.1(B), plus a civil penalty of not less than \$11,181 or more than \$22,363 as provided by Okla. Stat. tit. 63, § 5053.1(B) and adjusted for inflation, to the extent such multiplied penalties shall fairly compensate the State of Oklahoma or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(o) That judgment be entered in Relator's favor and against Defendants for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Tex. Hum. Res.

Code Ann. § 36.052(a), multiplied as provided for in Tex. Hum. Res. Code Ann. § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date that restitution is made to the State of Texas, pursuant to Tex. Hum. Res. Code Ann. § 36.052(a)(2), plus a civil penalty of not less than \$11,181 or more than \$22,363, pursuant to Tex. Hum. Res. Code Ann. §§ 36.052(a)(3) and adjusted for inflation, to the extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(p) That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in Va. Code Ann. § 8.01-216.3(A), plus a civil penalty of not less than five thousand five hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) as provided by Va. Code Ann. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of Virginia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

(q) That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

(r) That judgment be granted for Relator against Defendants for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relator in the prosecution of this suit; and

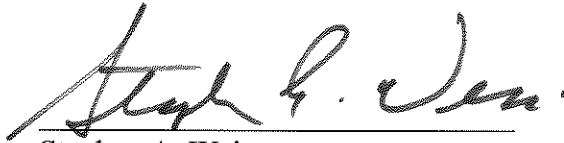
(s) That Relator be granted such other and further relief as the Court deems just and proper.

**JURY TRIAL DEMAND**

Relator demands a trial by jury of all issues so triable.

Dated: May 23, 2018

SEEGER WEISS LLP

A handwritten signature in black ink, appearing to read "Stephen A. Weiss", is written over a horizontal line.

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